- 233. The apparatus of claim 232, wherein said disc penetrating member has a tapered leading end to facilitate placement of said disc penetrating member into the disc space.
- 234. The apparatus of claim 139 in combination with a tap for insertion through said guard member for tapping the two adjacent vertebral bodies.
- 235. The apparatus of claim 139, further comprising an extractor coupler having one end adapted to couple with said guard member and an opposite end adapted to couple with an extraction device.
- 236. The apparatus of claim 139, wherein said portion of said disc penetrating extension has a height less than the height of said body and a length that is less than the transverse width of the vertebral bodies, said length being greater than the depth of the spinal disc intermediate the two adjacent vertebral bodies between which said disc penetrating extension is inserted.—.

REMARKS

The Examiner objected to claims 102-107, 114, 115, 122, 123, 128, 131, and 138 as being dependent upon a rejected base claim, but indicated that the aforementioned claims would be allowable if re-written in independent form. Applicant has re-written claims 102, 114, 115, 131, and 138 in independent form as suggested by the Examiner.

Claims 136 and 139 have been amended to better define Applicant's claimed invention.

Applicant notes that the Examiner withdrew claims 90 and 140 from consideration. Applicant draws the Examiner's attention to the Response to Restriction Requirement filed March 11, 1999 in which Applicant further elected Group I, claims 90

and 140 pursuant to 37 C.F.R. 1.129(b). Applicant respectfully submits that the Examiner improperly withdrew claims 90 and 140, and that Applicant is entitled to have claims 90 and 140 examined on their merits. Applicant notes that the Examiner indicated claim 90 to be allowable in the Office Action dated May 26, 1998. Applicant subsequently amended claim 90 to correct minor informalities as noted in the remarks of the reply dated November 23, 1998.

Applicant also notes that the Office Action fails to address Applicant's arguments submitted in the reply dated February 28, 2000. Since no new grounds of rejection were raised, Applicant submits that the Office Action is improper for lack of completeness and clarity pursuant to 37 C.F.R. § 1.104(a)(2), (b), and (c)(2). Applicant also submits that the Office Action is improper for being non-responsive to Applicant's arguments in contradiction to MPEP § 707.07(f). Applicant respectfully requests the Examiner to issue a non-final Office Action of the claims of Groups I and II on the merits.

With respect to the Examiner's rejection of claims 95-101, 108-113, 116-121, 124-127, 129, 130, and 132-136 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,878,915 to Brantigan ('915), the remarks from Applicant's reply dated February 28, 2000 are hereby incorporated herein.

With respect to the Examiner's rejection of claim 139 under 35 U.S.C. § 102(b) over Brantigan '915, claim 139 has been amended to recite that the guard member has at least one passageway "adapted to permit the passage of a bone removal device therethrough." The drill guard of Brantigan '915 does not disclose a "disc penetrating extension extending from said distal end of said guard" and "being separable from said

proximal end of said guard" as recited in independent claim 139 (see, e.g., Fig. 4 of Brantigan '915).

With respect to the Examiner's rejection of claim 137 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan '915 in view of Goble '286, the Examiner concedes that Brantigan '915 does not teach a tap. The Examiner continues in paragraph 4 of the Office Action by stating that the tap of Goble '286 could be substituted "for a self-tapping screw as disclosed by Brantigan because both devices are functionally equivalent with respect to forming a threaded opening in a vertebrae." However, Brantigan '915 does not teach a self-tapping screw. Brantigan '915 teaches that the implant itself has a "tapped hole 19" (see Col. 6, line 46). It is submitted that an implant with a tapped hole is not functionally equivalent to a tap for tapping two adjacent vertebral bodies.

Applicant submits that independent claims 95, 108, and 139 are allowable over Brantigan '915. Dependent claims 96-107 and 109-138, are allowable at least due to their dependency from allowable independent claims 95 and 108, respectively. It is submitted that the rejection of claims 95-101, 108-113, 116-121, 124-127, 129, 130, 132-136, and 139 under 35 U.S.C. § 102(b) as being anticipated by Brantigan '915 and the rejection of claim 137 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan '915 in view of Goble '286 have been overcome.

In view of the foregoing remarks, it is respectfully submitted that the claims 90 and 95-236 are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely notice of allowance of the claims is earnestly solicited.

If there are any fees due in connection with the filing of this response, please charge our Deposit Account Number 50-1068. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for in the papers accompanying this response, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

MARTIN & FERRARO LLP

Date: July 26, 2001

14500 Avion Parkway, Suite 300 Chantilly, VA 20151-1101 Telephone: 703-679-9300

Fax: 703-679-9303

Thomas H. Martin

Registration No. 34, 383 Attorney for Applicant(s)

CLAIM CHANGES

102. (Amended) [The spinal distractor of claim 95, in combination with] An apparatus for use in spinal fusion surgery, said apparatus comprising:

a spinal distractor for positioning adjacent vertebral bodies of two adjacent vertebrae adjacent a disc space in selected relationship to each other, said spinal distractor comprising:

at least one disc penetrating extension extending from said body for insertion into the lateral aspect of the disc space from a position anterior to the transverse processes of the adjacent vertebrae, said disc penetrating extension having a portion for bearing against each of the adjacent endplates of the two adjacent vertebral bodies, said portion of said disc penetrating extension having a height less than the height of said body and a length that is less than the transverse width of the vertebral bodies, said length being greater than the depth of the spinal disc intermediate the two adjacent vertebral bodies between which said disc penetrating extension is inserted; and

a guard having an opening for providing protected access to the disc space and the adjacent vertebral bodies, said spinal distractor passing through said opening.

114. (Amended) [The apparatus of claim 111, wherein] An apparatus for use in human spinal surgery across a disc space between the vertebral bodies of two adjacent vertebrae, comprising:

a guard member having a height greater than the height of the disc space and an opening for providing protected access to the lateral aspect of the disc space and the adjacent vertebral bodies from a position anterior to the transverse processes of the adjacent vertebrae, said opening having a maximum height; and

at least two disc penetrating extensions extending from said guard member for insertion into the lateral aspect of the disc space from a position anterior to the transverse processes of the adjacent vertebrae, said disc penetrating extensions having a portion for bearing against each of the adjacent endplates of the adjacent vertebral bodies, said portion of said disc penetrating extensions having a height less than the height of said guard member and a length that is less than the transverse width of the vertebral bodies, said length being greater than the depth of the disc space, said portion of said disc penetrating extensions having an upper surface adapted to contact one of the adjacent endplates of the adjacent vertebral bodies and a lower surface adapted to contact the other of the adjacent endplates of the adjacent vertebral bodies at more than one point through the disc space, said disc penetrating extensions [are] being of a different height.

115. (Amended) [The apparatus of claim 111, wherein] An apparatus for use in human spinal surgery across a disc space between the vertebral bodies of two adjacent vertebrae, comprising:

a guard member having a height greater than the height of the disc space and an opening for providing protected access to the lateral aspect of the disc space and the

adjacent vertebral bodies from a position anterior to the transverse processes of the adjacent vertebrae, said opening having a maximum height; and

at least two disc penetrating extensions extending from said guard member for insertion into the lateral aspect of the disc space from a position anterior to the transverse processes of the adjacent vertebrae, said disc penetrating extensions having a portion for bearing against each of the adjacent endplates of the adjacent vertebral bodies, said portion of said disc penetrating extensions having a height less than the height of said guard member and a length that is less than the transverse width of the vertebral bodies, said length being greater than the depth of the disc space, said portion of said disc penetrating extensions having an upper surface adapted to contact one of the adjacent endplates of the adjacent vertebral bodies and a lower surface adapted to contact the other of the adjacent endplates of the adjacent vertebral bodies at more than one point through the disc space, said disc penetrating extensions [are] being of a different length.

131. (Amended) [The apparatus of claim 130, wherein] An apparatus for use in human spinal surgery across a disc space between the vertebral bodies of two adjacent vertebrae, comprising:

a guard member including a hollow tube having a height greater than the height of the disc space and an opening for providing protected access to the lateral aspect of the disc space and the adjacent vertebral bodies from a position anterior to the transverse processes of the adjacent vertebrae, said opening having a maximum height, said hollow tube [has] having a detachable distal end portion; and

at least one disc penetrating extension extending from said guard member for insertion into the lateral aspect of the disc space from a position anterior to the transverse processes of the adjacent vertebrae, said disc penetrating extension having a portion for bearing against each of the adjacent endplates of the adjacent vertebral bodies, said portion of said disc penetrating extension having a height less than the height of said guard member and a length that is less than the transverse width of the vertebral bodies, said length being greater than the depth of the disc space, said portion of said disc penetrating extension having an upper surface adapted to contact one of the adjacent endplates of the adjacent vertebral bodies and a lower surface adapted to contact the other of the adjacent endplates of the adjacent vertebral bodies at more than one point through the disc space.

- 136. (Amended) The apparatus of claim [108] 135, wherein said disc penetrating [extension] member has a tapered leading end to facilitate placement of said disc penetrating [extension] member into the disc space.
- 138. (Amended) [The apparatus of claim 108, further comprising] An apparatus for use in human spinal surgery across a disc space between the vertebral bodies of two adjacent vertebrae, comprising:

a guard member having a height greater than the height of the disc space and an opening for providing protected access to the lateral aspect of the disc space and the adjacent vertebral bodies from a position anterior to the transverse processes of the adjacent vertebrae, said opening having a maximum height;

at least one disc penetrating extension extending from said guard member for insertion into the lateral aspect of the disc space from a position anterior to the transverse processes of the adjacent vertebrae, said disc penetrating extension having a portion for bearing against each of the adjacent endplates of the adjacent vertebral bodies, said portion of said disc penetrating extension having a height less than the height of said guard member and a length that is less than the transverse width of the vertebral bodies, said length being greater than the depth of the disc space, said portion of said disc penetrating extension having an upper surface adapted to contact one of the adjacent endplates of the adjacent vertebral bodies and a lower surface adapted to contact the other of the adjacent endplates of the adjacent vertebral bodies at more than one point through the disc space; and

an extractor coupler having one end adapted to couple with said guard member and an opposite end adapted to couple with an extraction device.

139. (Amended) An apparatus for use in human interbody spinal surgery across a disc space between the vertebral bodies of two adjacent vertebrae, comprising:

a guard member having <u>a proximal end</u>, a distal end, a height greater than the height of the disc space, and at least one passageway <u>adapted to permit the passage of a bone removal device therethrough</u> for providing protected access to the disc space and the adjacent vertebral bodies, said passage having a maximum height; and

at least one disc penetrating extension extending from said distal end of said guard member for insertion into the disc space, said disc penetrating extension being separable from said proximal end of said guard, said disc penetrating extension having

a portion for bearing against each of the adjacent endplates of the adjacent vertebral bodies, said portion of said disc penetrating extension having an upper surface adapted to contact one of the adjacent endplates of the adjacent vertebral bodies and a lower surface adapted to contact the other of the adjacent endplates of the adjacent vertebral bodies intermediate the two adjacent vertebral bodies between which said disc penetrating extension is inserted.